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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                  | CONFIRMATION NO.            |
|--|-------------|----------------------|--------------------------------------|-----------------------------|
| 10/524,028   | 02/09/2005  | Jason Witherington   | 0020-5339PUS1                        | 4861                        |
| 2292 7590 09/06/2007<br>BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | EXAMINER<br>DAVIS, ZINNA NORTHINGTON |                             |
|  |             |                      | ART UNIT<br>1625                     | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>09/06/2007      | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

|                              |                         |                     |  |
|------------------------------|-------------------------|---------------------|--|
| <b>Office Action Summary</b> | Application No.         | Applicant(s)        |  |
|                              | 10/524,028              | WITHERINGTON ET AL. |  |
|                              | Examiner                | Art Unit            |  |
|                              | Zinna Northington Davis | 1625                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 7 and 9-12 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 5, 8, 13, and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. <u>20070829</u> .                           |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date <u>see continuation sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____.                          |

3) February 9, 2005, September 7, 2005, and December 11, 2006

### DETAILED ACTION

1. Claims 1-18 are pending.
2. The Preliminary Amendment filed February 9, 2005 has been considered.
3. In the response filed June 21, 2007, Applicants have elected Group I, claims 1-14, without traverse.
4. Claims 15-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
7. Claims 1, 4, 6, and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A. At claim 1, it is suggested that the phrase "a pharmaceutically acceptable derivative thereof:" should be amended to read in favor of:

"a pharmaceutically acceptable salt thereof."

B. At claim 4, it is suggested that the phrase "combine together to form a ring including piperidinyl, piperazinyl, pyrrolidinyl or morpholinyl group"(all occurrences) should be amended to read in favor of:

"combine together to form a ring selected from piperidinyl, piperazinyl, pyrrolidinyl and morpholinyl group".

C. At claims 6 and 11, it is suggested that the claims should be written in Independent form or the radicals should be defined.

D. At claim 7, last line, it is suggested that the phrase "as defined in claim 1" should be deleted. This phrase is redundant.

E. At claim 9, it is suggested that the compounds defined by E1- E51 should be defined.

F. At claim 10, it is suggested that the compounds defined by E5, E9, E32, E41, E42, and E511 should be defined.

G. Claims 12 and 1 are identical. Is a method of treatment intended?

Clarification Is appreciated.

8. Claims 2, 3, 5, 8, 13, and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The Information Disclosure Statements filed February 9, 2005, September 7, 2005, and December 11, 2006 have been considered. The references alone or in combination forms do not teach nor suggest the structurally similar compounds as the

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instantly claimed compounds. There is no motivation to modify the prior art compounds to derive those instantly claimed. As such, no rejections based upon prior art are made.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

11. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Zinna Northington Davis**  
**Primary Examiner**  
**Art Unit 1625**